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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-------------------------------------|-----------------|----------------------|-------------------------|-----------------|
| 10/812,638 | 03/29/2004 | Mario Abdennour | 25669-014 CIP CON | 3493 |
| 30623 7 | 7590 01/26/2005 | | EXAMINER | |
| MINTZ, LEVIN, COHN, FERRIS, GLOVSKY | | | BUMGARNER, MELBA N | |
| AND POPEO, ONE FINANC | IAL CENTER | | ART UNIT | PAPER NUMBER |
| BOSTON, MA 02111 | | | 3732 | |
| | | | DATE MAILED: 01/26/2005 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|---|---|------------------|--|--|--|--|--|
| Office Astion Occurrence | 10/812,638 | ABDENNOUR ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Melba Bumgarner | 3732 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on | Responsive to communication(s) filed on | | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This | his action is FINAL. 2b) This action is non-final. | | | | | | |
| , = - | · · · · · · · · · · · · · · · · · · · | | | | | | |
| closed in accordance with the practice under E | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-20</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1-20</u> is/are rejected. | | | | | | | |
| , | Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. <u>09/963,880</u> . 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
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| | | . - | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) A) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | | |
| 3) Notice of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152) | | | | | | | |
| Paper No(s)/Mail Date <u>3/29/04</u> . 6) Other: | | | | | | | |

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 7, and 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,712,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 1-5, 7, and 15-20 of the application and claims 1-13 of the patent lies in the fact that the patent claim includes many more elements and is thus more specific. Thus the invention of the claims of the patent is in effect a "species" of the "generic" invention of the claims of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1-5, 7, and 15-20 are anticipated by claims 1-13 of the patent, it is not patentably distinct from claim PP.

Claim Objections

3. Claims 3, 4, 9, 11, and 13 are objected to because of the following informalities: Claim 3 is objected to for misspelling of "tetracycline". Recitation of "the antibiotic" in claim 4, "the

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root canal", "the treatment site" and "the antibiotic" in claim 9, and "the treatment site" in claims 11 and 13 lack sufficient antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 2, 3, 5, and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 contains an improper Markush expression, also "form" in line 1 should read –from---. In claims 15-18, it is unclear what is meant by the percentage.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodson (4,892,736). Goodson discloses a fiber comprising a copolymer vehicle having incorporated therein one or more medicaments (column 3 line 30). Patentable weight is not given to the intended use of the fiber. As to claims 2 and 3, the medicament is antibiotic of tetracycline (column 6 line 37). As to claim 5, Goodson shows a combination of antibiotic and anti-inflammatory agent (column 6 line 53).

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson in view of Damani (5,114,718). Goodson discloses a fiber that shows the limitations as described above and the vehicle is an ethylene vinyl acetate copolymer (column 4 line 63) having a diameter of 0.1 to about 1 mm; however, Goodson does not show medicament of clindamycin. Damani teaches devices providing medicament of clindamycin (column 2 line 65) as well as tetracycline (column 2 line 64). It would have been obvious to one having ordinary skill in the art to incorporate medicament of clindamycin to the fiber of Goodson, since Damani discloses both as known antibiotics. As to the dose of antibiotic, Damani teaches steady state average concentrations of medicament of about 10 µg to 5000 µg per device.
- 10. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson. Goodson discloses obtaining a fiber having one or more medicaments incorporated therein that is suitable for intracanal use, positioning the fiber such that the fiber is in direct contact with a treatment site, and maintaining the fiber at the treatment site, wherein the medicament is delivered to the treatment site at a controlled rate (column 2 line 56); however, Goodson does not show the step of the fiber in the root canal. It would have been obvious to one of ordinary skill in the art to do so, since one skilled in the art would recognize that the fiber of Goodson is of a

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size and characteristics sufficient for positioning in a root canal and Goodson shows method of localized treatment within the oral cavity.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson in view of Hoyt et al. (4,003,810). Goodson discloses a fiber as described above and of ethylene vinyl acetate copolymer (column 4 line 63); however, Goodson does not show less than about 20% vinyl acetate. Hoyt et al. disclose a fiber (column 3 line 7) of ethylene vinyl acetate copolymer comprising 3 to 50 percent vinyl acetate. It is held to be an obvious matter of choice to one of ordinary skill in the art as to the specific amount of a known material and as to its intended use.

Conclusion

- 12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goodson (4,175,326) and Golub et al. (4,666,897) are cited to show the state of the art with respect to dental fiber and dental medicament, respectively.
- This is a continuation of applicant's earlier Application No. 09/963,880. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melba Bunganer Melba Bumgarner

Patent Examiner